

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO: 05-10048-REK

U.S. DISTRICT COURT
DISTRICT OF MASS.

LAUREN FLORO,)
Plaintiff,)
v.)
METABOLIFE INTERNATIONAL INC.,)
WALGREEN CO., and)
WALGREEN EASTERN CO.)
Defendants.)

**PLAINTIFF LAUREN FLORO'S OPPOSITION TO DEFENDANTS'
MOTION FOR LEAVE TO ALLOW DEFENDANTS TO SERVE ANSWERS LATE**

Plaintiff Lauren Floro (“Ms. Floro”) hereby opposes and responds to the Opposition of Defendants To Plaintiff’s Request For Entry Of Default, and Defendants’ Motion For Leave To Allow Defendants To Serve Answers Late (the “Motion”). A default against defendants should enter, pursuant to Fed. R. Civ. P. 55(a), and such default should not be set aside. Defendants have failed to submit evidence sufficient to establish a meritorious defense to Ms. Floro’s claims. The only stated bases for the purported “meritorious defense” are: (1) defendants’ selectively chosen, misconstrued quotations from an outdated study occurring before the U.S. Food and Drug Administration (“FDA”) found the key ingredient in Metabolife’s product dangerous, and (2) irrelevant information about ongoing *Daubert* hearings in a case pending in another jurisdiction. Because defendants have failed to establish any meritorious defense to Ms. Floro’s claims as required to obtain the requested relief, defendants’ Motion should be denied.

PROCEDURAL HISTORY

1. On or about September 16, 2004, Ms. Floro filed her Complaint in the Commonwealth of Massachusetts Superior Court, Middlesex County.
2. On or about September 30, 2004 Ms. Floro served a demand letter pursuant to M.G.L. c. 93A upon defendants in this matter.
3. On or about November 4, 2004, defendants responded to Ms. Floro's letter. No settlement offer was made pursuant to M.G.L. c. 93A.
4. On or about December 6, 2004, plaintiff's counsel requested in writing that defendants' counsel accept service on behalf of their clients.
5. On or about December 9, 2004, Nicholas Alexander, Esq., counsel for defendants, declined to accept service on defendants' behalf.
6. On or about December 10, 2004, plaintiff Lauren Floro filed her First Amended Complaint in the Commonwealth of Massachusetts Superior Court, Middlesex County, adding defendant Walgreen Eastern Co. as a party.
7. On or about December 10, 2004, defendant Metabolife International, Inc. was served in-hand via Sheriff of the County of San Diego, California, via certified mail with return receipt, and via Federal Express. On or about December 10, 2004, defendants Walgreen Co. and Walgreen Eastern Co. were served in-hand via court appointed process server, via certified mail with return receipt, and via Federal Express.
8. On or about December 29, 2004, defendants' counsel requested and plaintiff's counsel agreed to a two-week extension to file Answers to the First Amended Complaint.
9. On or about January 6, 2005, defendants filed a Notice of Removal To The United States District Court.

10. On January 14, 2005, Attorney Racette requested and plaintiff's counsel agreed to an additional week extension to January 21, 2005, for the defendants' Answers to be served.

11. On Friday, January 21, 2005, Attorney Racette requested and plaintiff's counsel agreed to a third extension for the defendants to file Answers, to Monday, January 24, 2005.

12. The defendants did not file or serve their Answers on January 24, 2005 as agreed. Attorney Racette did not contact plaintiff's counsel to request any additional extension.

13. On Tuesday, January 25, 2005, plaintiff's counsel telephoned Attorney Racette to ask the status of the defendants' Answers. Whereupon, Attorney Racette requested a fourth extension of time to Wednesday, January 26, 2005 for the defendants to file their Answers.

14. Plaintiff's counsel agreed to Attorney Racette's fourth request for an extension, until Wednesday, January 26, 2005, notwithstanding that the defendants had failed to file their Answers by the third extended deadline and also failed to contact plaintiff's counsel to request an additional extension.

15. As of Thursday, January 27, 2005, counsel for the plaintiff had not been served with any responsive pleadings by the defendants, despite the agreed-upon deadline of Wednesday, January 26, 2005.

16. On January 27, 2005, Ms. Floro's counsel filed a Request for Entry of Default, one day after the Wednesday, January 26, 2005 extension deadline passed without service of Answers.

17. At no time did counsel for Ms. Floro agree to Friday, January 28, 2005 as the deadline for Answers to be received.

18. Ms. Floro has complied with all deadlines, statutes of limitations, service rules, and tracking orders.

FACTUAL BACKGROUND

The following is a summary of facts alleged in Ms. Floro's First Amended Complaint.

Metabolife's product, Metabolife 356, is a dietary supplement product containing ephedra. Products containing ephedra have been linked to, among other things, a substantial increase in heart rate, a substantial increase in blood pressure, stimulation of the central nervous system, palpitations, arrhythmias, dysrhythmias, hypertension, myocardial infarctions, intracranial hemorrhage, tachycardia, heart attack, strokes, and death.

In or about July 2001, Ms. Floro purchased Metabolife 356 from a Walgreens store in Waltham, Massachusetts. On or about September 23, 2001, Ms. Floro ingested Metabolife 356 in a manner consistent with Metabolife's instructions. Later that day, Ms. Floro suffered a stroke. At the time of her stroke, Ms. Floro was twenty-one years old. In connection with that stroke, Ms. Floro has suffered significant personal injuries as a result of taking Metabolife's ephedra-containing product Metabolife 356.

Metabolife received more than three hundred reports of serious adverse health events from 1995 through 1999 but failed to report them to the FDA. Metabolife did not inform the U.S. Government about any reports of adverse health events received until the Government intervened. In its analysis of documents obtained from Metabolife, authorities found that between May 1997 and July 2002, Metabolife received over 14,000 reports from consumers or other individuals complaining of adverse health events or serious adverse events associated with the ingestion of Metabolife 356.

As of September 27, 2002, the FDA had received approximately 1,800 Adverse Event Reports from consumers or other individuals complaining of adverse health events or serious

adverse events associated with the ingestion of dietary supplements containing ephedra, including approximately 322 Adverse Event Reports from consumers or other individuals complaining of adverse health events or serious adverse events associated with the ingestion of Metabolife 356.

In 1995, a subcommittee of the FDA agreed that the use of certain ephedra-containing dietary supplements might cause consumers to experience serious adverse events. In 1996, a majority of the Food Advisory Committee of the FDA stated that, based on the increasing number of Adverse Event Reports, no safe level of ephedrine alkaloids could be identified for use in dietary supplements. At that time, a majority of the Food Advisory Committee of the FDA recommended that the FDA take steps to remove dietary supplements containing ephedra from the market. The FDA officially banned products containing ephedra as of April 12, 2004.

ARGUMENT

1. Legal Standard to Establish Good Cause to Set Aside Default.

To set aside an entry of default pursuant to Fed. R. Civ. P. 55(c), the moving party must show good cause, including establishing a meritorious defense. Coon v. Grenier, 867 F.2d 73, 77 (1st Cir. 1989) (holding moving party established “meritorious defense” where he filed a separate affidavit suggesting the existence of facts which, if proven at trial, would constitute a cognizable defense). Where the moving party’s “stonewalling” reveals a lack of valid defense, a 55(c) motion will be denied. Assocs. v. Designs by FMC, Inc., 318 F.3d 1, 15 (1st Cir. 2003) (motion denied for lack of meritorious defense where court “felt that [moving party] was merely trying to postpone the inevitable”). To set forth grounds for a meritorious defense, at a minimum, the opposing party must establish facts beyond “purely conclusory” allegations, which reasonably set forth a basis for recovery. Teamsters, Chauffeurs, Warehousmen and Helpers

Union, Local No. 59 v. Superline Trans. Co., Inc., 953 F.2d 17, 21 (1992) (determining moving party failed to “establish that it possesses a potentially meritorious claim or defense, which, if proven, will bring success in its wake”). While the party need not establish an ironclad claim or defense guaranteeing success at trial, “such a showing requires more than an unsubstantiated boast” to survive. Id.

2. **Defendants Failed To Establish A Meritorious Defense.**

Defendants’ reliance on selected excerpts of the Rand study falls far short of establishing a meritorious defense for the purpose of setting aside a default. The defendants ignore the undeniable and critical fact that, subsequent to publication of the Rand study, the FDA banned products containing ephedra, including Metabolife 356, due to unreasonable health risks such as strokes and death. The FDA based its determination, among other things, on overwhelming data contained in over 16,000 pages of documents from Metabolife’s own call records. The FDA’s Final Rule banning ephedra, appearing in the Federal Register on February 11, 2004, confirmed that, “dietary supplements containing ephedrine alkaloids are adulterated under . . . (21 U.S.C. 342(f)(1)(A)) . . . because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use.” *Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk*, 69 Fed. Reg. 6787 (Feb. 11, 2004) (codified at 21 C.F.R. § 119.1 (2004)).

Contrary to the defendants’ contentions of a meritorious defense, the FDA Final Rule has the effect of establishing that Metabolife’s ephedra-containing dietary supplement product presented an unreasonable risk of injury or illness to consumers. See 44 U.S.C. § 1507 (“the contents of the Federal Register shall be judicially noticed”); *McCormick on Evidence* (5th ed.) §

335 (1999) (when [state and national administrative regulations] are published in the Federal Register it is provided that their contents shall be judicially noticed"). Therefore, defendants' statements, such as "the majority of FDA case reports are insufficiently documented to make an informed judgment about the relationship between the use of ephedra-containing dietary supplements and the adverse event in question" and "[RAND] was unable to determine that ephedra-containing dietary supplements resulted in any serious adverse events in its users," fail to establish a meritorious defense in light of the FDA's proclamation, codified in the Federal Register, declaring that products containing ephedra create an unreasonable risk of illness or injury and ordering products such as Metabolife 356 be removed from the marketplace. Thus, defendants' purported meritorious defense consists of nothing more than conclusory allegations and irrelevant and obsolete facts.

Moreover, the Rand study was specifically cited by the FDA in support of its determination to ban ephedra. The FDA's February 28, 2003 Fact Sheet regarding dietary supplements containing ephedra stated that "in conjunction with other recent studies of serious adverse events involving persons taking ephedra, the RAND study adds significantly to the evidence suggesting that ephedra as currently marketed may be associated with unreasonable safety risks."

In July 2003, the U.S. General Accounting Office ("GAO") summarized the many studies analyzing ephedra-related reports during testimony before a House Subcommittee on the effects of ephedra. As stated in the FDA's Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk:

GAO's testimony discussed and updated some of its findings from its prior 1999 report on dietary supplements containing ephedrine alkaloids. The testimony provided new information, including an evaluation of Metabolife International's records of health-related calls from consumers of Metabolife 356. GAO noted

that the types of adverse events identified in the health-related call records from Metabolife International were consistent with the types of adverse events reported to [the FDA], as well as with the scientifically documented physiological effects of ephedrine alkaloids.

GAO also noted that despite limited information contained in most of the call records, 14,684 call records contained reports of at least one adverse event among consumers of Metabolife 356. The GAO testimony identified 92 serious events that included heart attacks, strokes, seizures, and deaths and emphasized that these findings were similar to other reviews of the call records, including those done by Metabolife International and its consultants. The GAO testimony noted that, in those call records where age was documented, many of the serious adverse events occurred in relatively young customers, with more than one-third being under the age of 30. Further, for those call records in which quantity of use and/or frequency and duration of use were noted, most of the serious adverse events occurred among Metabolife 356 users who used the product within the recommended guidelines.

69 Fed. Reg. at 6791 (emphasis added). Defendants submit nothing, by affidavit or otherwise, to refute the many serious adverse health events experienced by consumers of Metabolife 356, including those like Ms. Floro who are under the age of 30 and used the product within the recommended guidelines. Thus, defendants' Motion fails to establish a meritorious defense to Ms. Floro's claims.

To the extent that defendants also base their meritorious defense argument on the mere existence of a pending Metabolife motion to disqualify on *Daubert* grounds an expert witness for another plaintiff in another action in another jurisdiction, *i.e.*, the MDL proceeding In Re: Ephedra Products Liability Litigation in the United States District Court for the Southern District of New York, that matter and any undecided motions in connection with it are simply of no consequence here.

3. Plaintiff's Counsel Never Assented to an Extension to January 28, 2005.

In their Motion, at page 6, the defendants state that "the Defendants' counsel believed that the Plaintiff's attorney had agreed to an enlargement to the end of the week [January 28, 2005], even though he hoped to have them earlier, rather than later, in the week." Plaintiff's

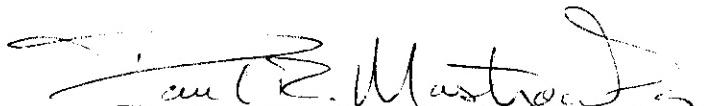
counsel, however, agreed to no such thing. There was no ambiguity in the agreement by plaintiff's counsel to extensions through Monday, January 24, 2005, and later to Wednesday, January 26, 2005. Both such dates passed without service of responsive pleadings or even contact from defendants' counsel to request a further extension. It appears that defendants' counsel is suggesting that despite the fact that the parties agreed to set two specific prior dates as deadlines, those deadlines had no significance and the true deadline was a later date never specifically discussed or agreed to. This defies common sense. In these circumstances, the Court should consider the distinct possibility that there was no "misunderstanding" as the defendants' counsel claims, but instead that the defendants willfully disregarded not one, but two agreed extension deadlines.

While Ms. Floro does not claim to have suffered actual prejudice at this early stage of the case as a result of defendants' twice failing to serve their responsive pleadings, this Court should not countenance the defendants' actions and their apparent disregard of the case deadlines, especially where no meritorious defense exists.

Conclusion

For all of the foregoing reasons, plaintiff Lauren Floro respectfully requests that the defendants' Motion be denied.

LAUREN FLORO, PLAINTIFF
By her attorneys,


Robert J. O'Regan, Esq., BBO #379970
Paul R. Mastrocola, Esq., BBO #630664
Diane A. D. Noel, Esq., BBO#656430
Burns & Levinson LLP
125 Summer Street
Boston, Massachusetts 02110-1624
(617) 345-3000

Dated: February 9, 2005

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document
was served upon the attorney of record for each party
by mail ~~on~~ on February 7, 2005.

